



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,529	03/05/2007	Conrad L. Cowan	067437-5021US	4717
67374 7590 07/31/2009 MORGAN, LEWIS & BOCKIUS, LLP ONE MARKET SPEAR STREET TOWER SAN FRANCISCO, CA 94105			EXAMINER ULM, JOHN D	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 07/31/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,529	Applicant(s) COWAN, CONRAD L.	
	Examiner John D. Ulm	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-61 and 63-73 is/are pending in the application.
- 4a) Of the above claim(s) 48-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61 63-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- 1) Claims 48 to 61 and 63 to 73 are pending in the instant application. Claims 61, 63 to 65, 67 and 68 have been amended and claim 62 canceled as requested by Applicant in the correspondence filed 29 April of 2009.
- 2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

- 4) Claims 48 to 60 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12 December of 2008. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

- 5) Claims 61, 63 to 66 and 68 to 73 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirements for those reasons of record in the office action mailed 29 January of 2009. As stated therein, 61 to 66 and 68 to 73, in so far as these claims encompass a method that employs a "conjugate associated with the desensitization pathway of" a G protein-coupled receptor, the only such compound that is described in the instant specification

Art Unit: 1649

or the art of record **that is capable of functioning in the context of the instant invention** is a conjugate comprising an arrestin protein. No other functional conjugate is suggested or described by the instant specification or the prior art of record.

Applicant has traversed this rejection on the premise that “several examples of proteins associated with the desensitization pathway are known in the art and described in the instant specification” “including not only arrestin but also GRKs, GPCRs, AP-2 protein, clathrin, protein phosphatases, as well as other molecules”. This is not persuasive because the mere recitation of a plurality of proteins known to be involved with GPCR desensitization does not constitute a written description of those proteins capable of functioning in the context of the claimed invention. To be operable, a conjugate comprising a marker molecule and a protein that is associated with the desensitization pathway of a GPCR must remain detectably associated with an agonist-activated form of the GPCR. Whereas “GRKs, GPCRs, AP-2 protein, clathrin, protein phosphatases, as well as other molecules” may be involved with GPCR desensitization, there is absolutely no evidence that they remain physically associated with an agonist activated GPCR for sufficient time as to permit detection. Neither the instant specification nor the art of record describes even a single working example of a method of measuring GPCR activation by employing a detectably labeled protein “that is associated with the desensitization pathway of a GPCR” wherein that protein is not arrestin. *In re Clarke*, 148 USPQ 665, (CCPA 1966) held that;

“ It appears to be well settled that a single species can rarely, if ever, afford support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do

Art Unit: 1649

not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of a small genus such as halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably large number of reductions to practice would probably be necessary."

In addition, Applicant is advised that a patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc. v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed method with any detectably labeled protein "that is associated with the desensitization pathway of a GPCR" wherein that protein is not arrestin without first making a substantial inventive contribution. Applicant's argument that "the present specification provides working examples of multiplex receptor assays in which different conjugates are described and used to analyze different test compounds" ignores the fact that the protein "associated with the

Art Unit: 1649

desensitization pathway of a GPCR” which was employed in each and every one of those working examples was an arrestin.

Claim Rejections - 35 USC § 102

6) Claims 61 and 63 to 73 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Barak et al. patent (5,891,646) for those reasons of record in the office action mailed 29 January of 2009. As stated therein, Barak et al., in its entirety, described a method of detecting the activation of a G protein-coupled receptor (GPCR) in a cell by introducing into that cell an arrestin/green fluorescent protein (GFP) conjugate and measuring the translocation of GFP activity to the cell membrane upon agonist activation of the GPCR. The text in lines 19 to 28 in column 8 and in lines 34 to 47 in column 11 expressly taught the use of a cell expressing two or more different GPCRs in the method described therein.

Applicant has traversed this rejection on the premise that “Barak fails to describe or suggest a method of screening in which a cell comprises two different GPCRs and two different marker conjugates”. Whereas Barak does describe a cell comprising two different GPCRs, as conceded by applicant, nothing in the instant claims requires two different protein conjugates. Therefore, Applicant’s arguments are based upon a limitation that is not present in the claims, as evidenced by the limitations of dependent claims 67 and 68.

Further, even if such a limitation was recite, it would not be distinguishing because there is no evidence that any of the “GRKs, GPCRs, AP-2 protein, clathrin, protein phosphatases, as well as other molecules” listed in the instant specification

Art Unit: 1649

selectively associate with one GPCR to the exclusion of another. Therefore, such an embodiment would not allow one to determine which of a plurality of GPCRs expressed in a common host cell are activated by a particular compound and which aren't, since the activation of any GPCR in that cell would produce the same signal. The inclusion of multiple conjugates with different detectable labels would merely be redundant.

As explained in M.P.E.P. 2144.04, the mere duplication of parts in a known combination wherein that duplication does not produce an unexpected result does not constitute a patentable contribution over the prior art. See M.P.E.P. 2144.04(VI)(B) and *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960):

In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) (Claims at issue were directed to a water-tight masonry structure wherein a water seal of flexible material fills the joints which form between adjacent pours of concrete. The claimed water seal has a "web" which lies in the joint, and a plurality of "ribs" projecting outwardly from each side of the web into one of the adjacent concrete slabs. The prior art disclosed a flexible water stop for preventing passage of water between masses of concrete in the shape of a plus sign (+). Although the reference did not disclose a plurality of ribs, the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.).

Response to Arguments

7) Applicant's arguments filed 29 April of 2009 have been fully considered but they are not persuasive for those reasons given above.

Conclusion

8) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1649

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/572,529

Page 8

Art Unit: 1649

/John D. Ulm/

Primary Examiner, Art Unit 1649